MEMORANDUM OF PHILIP MORRIS INCORPORATED TO THE FEDERAL TRADE COMMISSION IN REPLY TO QUESTIONS RAISED BY THE COMMISSION'S STAFF IN CONNECTION WITH THE INVESTIGATION OF THE BARCLAY FILTER

Philip Morris Research Center
Richmond, Virginia

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INTRODUCTION AND SUMMARY

Philip Morris Incorporated submits this memorandum in response to the Commission's letter of December 15, 1981 regarding the Barclay filter investigation.[1/] In that letter, the Commission announced its determination "that the substantial evidence obtained to date raises serious questions regarding whether the [Commission's] current testing methodology assesses Barclay's 'tar' delivery accurately." The Commission also established a program for expedited resolution of these serious questions now clouding the integrity of the Commission's cigarette testing program.

We are submitting herewith the report of a leading independent testing organization, United States

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1/ When the Commission's investigation began, the five styles of Barclay were the only cigarettes employing the bypass filter. Use of the bypass filter has since spread, however, to other Brown & Williamson brands -- Kool Ultra and reportedly Viceroy Ultra Rich Lights -- and further proliferation may be imminent. References herein to "Barclay" should be understood, unless the context indicates otherwise, to apply to all brands fitted with the same type of filter.

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Testing Company, Inc. ("U.S. Testing"), on the results of that company's recent extensive study of cigarette dilution involving more than 500 smokers. The U.S. Testing report and this memorandum supplement and confirm the overwhelming body of scientific evidence already presented to the Commission establishing that the bypass filter employed on Barclay -- and now being installed by Brown & Williamson on other heavily promoted cigarette brands -- is duplicitous in its design and operation. Unlike any other filter that we have ever seen or examined, the Barclay filter functions one way in the Commission's smoking machine and in a radically different way in a smoker's lips. Effective corrective action by the Commission is urgently required.

In its letter of December 15, 1981, the Commission requested supplemental submissions focusing on two issues: (i) the methodology used in the dilution measurement studies previously submitted by Philip Morris, and (ii) the validity and relevance of the cotinine experiment submitted by Brown & Williamson Tobacco Corporation. We discuss more fully below the following points:

First, the Philip Morris dilution measurements dramatically demonstrate that Barclay, unlike any other brand, yields significantly lower dilution when smoked

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in the lips than in the Commission's machine. For that reason, Barclay's "tar" delivery is not comparable to that of other brands measuring 1 mg. by the current FTC method. As shown by our specific responses to each of the Commission's questions, the previously submitted dilution measurements are based on sound, scientific methods.

Second, the conclusions of the Philip Morris dilution study have been replicated and validated through a meticulous, large-scale, independent study, involving more than 500 smokers, designed and conducted in January and February 1982 by United States Testing Company, one of the nation's leading testing organizations. The U.S. Testing study, conducted pursuant to a request by Philip Morris, is described in detail below, and all of the data generated in the study are available to the Commission. This extensive survey demonstrates, beyond any doubt, that the dilution of Barclay drops dramatically when it is smoked in the lips; that this phenomenon does not occur in cigarettes without a Barclay-type filter; and that, when measured at its human dilution level, Barclay delivers about 8 mg. "tar" by FTC method. Contrary to Brown & Williamson's advertising, Barclay is not an ultra low "tar" cigarette.

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Third, Brown & Williamson's defense rests primarily on an experiment purportedly measuring the plasma cotinine levels in the blood of smokers involuntarily switched from 1 mg. "tar" cigarettes to Barclay. As explained below and in the accompanying letters from three eminent experts, Dr. Herbert McKennis, Dr. Paul Larson, and Dr. Neal Castagnoli, B&W's experiment is of no scientific value, and may not properly be relied upon to draw conclusions about the smoke deliveries of particular cigarette brands.

Fourth, it is noteworthy that B&W's own cotinine data -- unscientific as they are -- actually confirm the duplicitous character of Barclay. While the nicotine deliveries of Barclay, Carlton and Cambridge under current FTC machine smoking conditions are very similar, the plasma cotinine levels of smokers switched from Carlton or Cambridge to Barclay appeared to increase, frequently by as much as 100 to 200 percent or more. As noted by researchers in this area and acknowledged in B&W's papers, such an increase suggests that Barclay delivers many times more "tar" than Cambridge or Carlton.

The Commission has been investigating the Barclay filter for many months, and it has received extensive

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analyses and data from cigarette company research departments and from outside consultants. Particularly in view of the U.S. Testing report, there is now overwhelming evidence that the Commission's current testing methodology does not assess Barclay's "tar" delivery accurately. Because of Barclay's substantial dilution differential when smoked in the lips rather than in the Commission's current lip-less holding device, Barclay cannot and should not be ranked at the same level as other cigarettes measured at 1 mg. "tar" by FTC method. The complex and unsound cotinine experiment proffered by B&W provides, if anything, further confirmation of this conclusion. The Commission should not delay any further in taking the necessary action to restore and maintain the integrity of its cigarette testing program. Specifically, we urge that the Commission utilize in its cigarette testing laboratory the holding device recommended by Philip Morris to obtain accurate and reliable comparative "tar" data.

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DISCUSSION

I. LARGE-SCALE, SCIENTIFICALLY VALID DILUTION STUDIES DEMONSTRATE THAT BARCLAY DELIVERS SUBSTANTIALLY HIGHER "TAR" WHEN SMOKED IN THE LIPS THAN ANY OTHER CIGARETTE MEASURED AT 1 MG. "TAR" BY THE CURRENT FTC METHOD.

It is an accepted fact that cigarette dilution is a significant determinant of the delivery of "tar," nicotine, carbon monoxide, and other smoke components; indeed, in very low delivery cigarettes, dilution is by far the most significant determinant. Dilution and "tar" delivery are inversely related: the higher the dilution percentage, the lower the "tar" yield, and vice versa.

As we previously demonstrated in memoranda submitted to the Commission, when a Barclay cigarette is puffed on a smoking machine, the four peripheral air channels of the bypass filter produce an extremely high level of dilution air -- in excess of 70% -- with a concomitantly low "tar" delivery. However, when a Barclay cigarette is puffed in the lips of a smoker, there is substantial blockage or occlusion of the channels by the smoker's lips, and dilution drops dramatically, typically to the 45% range and often much lower. When Barclay's dilution is reduced to 45%, it

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becomes an 8 mg. "tar" cigarette by FTC method. No other cigarettes, except brands with a Barclay-type filter, experience any significant change in dilution when puffed in the lips.

In July 1981, Philip Morris submitted to the Commission the results of a study demonstrating the difference in the dilution of Barclay between machine and in-lip smoking. We have provided a detailed description of the development and operation of the Puff Parameter Analyzer ("PPA"), the on-line scientific equipment that measures the actual dilution of cigarettes puffed by human smokers. In addition, we have demonstrated the operation of the PPA to members of the Commission's staff and to representatives and scientific consultants of Brown & Williamson.2/

The aerodynamic and electronic design of the PPA equipment has not been questioned. As noted by Professor Sheila Widnall of the Massachusetts Institute

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2/ On August 26, 1981, at B&W's request, Philip Morris demonstrated the operation of the PPA at the home of a B&W engineering consultant in Cambridge, Massachusetts, to permit him to comment on the operation of the equipment. During that demonstration, representatives of both B&W and the Commission's staff puffed Barclay cigarettes on the PPA, and recorded drastically lower dilution when the cigarette was held in the lips than when it was puffed through a mouthpiece.

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of Technology, an eminent scientist and independent consultant who was asked to review the PPA, the dilution measurement equipment is not only well designed and constructed, but inherently more accurate than the equipment which is available to test the PPA.

The only questions that have been raised regarding the dilution study conducted by Philip Morris deal with the methodology used in that study. Those questions are answered below in detail. We shall demonstrate that the study conducted and the methodology employed by Philip Morris were sound, valid, and entirely sufficient to establish the duplicitous character of the bypass filter. In any event, any methodological questions raised about the Philip Morris dilution study have been obviated by the large-scale independent dilution study conducted by U.S. Testing.

A. The Large-Scale United States Testing Study

In order to resolve any question that might be raised regarding the methodology of the dilution studies submitted to the Commission by Philip Morris -- including the questions set forth in the Commission's letter of December 15, 1981 -- shortly after receiving the Commission's letter, we asked United States Testing

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Company to develop and conduct a large-scale study of Barclay's dilution.

Philip Morris provided U.S. Testing with three Puff Parameter Analyzers and instructed the testing company's scientific personnel in the machines' operation. We asked U.S. Testing's Consumer Research Division to design and conduct a study, with whatever controls it deemed appropriate, (i) to compare the dilution of Barclay when puffed in a smoker's lips with the dilution of Barclay when puffed in a mouthpiece, and (ii) to make the same dilution comparison for the smoker's own brand and for several other brands of varying dilution.

The basic study designed and conducted by U.S. Testing involved 500 smokers, a demographically selected sample reflecting the age, sex, and cigarette brand distribution of smokers in the population. U.S. Testing measured the dilution experienced by each smoker on five brands of cigarettes: the smoker's own brand, Barclay, Carlton, Merit and "Extended Filter," a special cigarette made by fitting an extra-long Barclay-type filter to a standard Cambridge tobacco rod.3/ Every

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3/ The Extended Filter cigarettes have the same bypass filter as Barclay except that the ventilation perforations are 17 millimeters from the mouth-end of the

[Footnote continued on following page]

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cigarette was puffed both while held in a mouthpiece -- so that the smoker's lips could not touch it -- and also while held directly in the lips.

1. Results of the United States Testing Study

The U.S. Testing study fully confirms the results of the earlier Philip Morris studies: that the dilution of Barclay-type cigarettes, alone among all brands, drops dramatically when those cigarettes are puffed in a human smoker's lips. When a Barclay-type cigarette is held in a mouthpiece and puffed, it produces a dilution similar to that produced in a smoking machine. When the mouthpiece is removed, however, Barclay becomes a very different cigarette.

The averages for 500 smokers are as follows:

Brand	Average Percent Dilution (cigarette held in mouthpiece)	Average Percent Dilution (cigarette held in lips)
Respondent's Own Brand	24.5	24.5
Carlton	69.1	69.5

[Footnote continued]
filter. When such a cigarette is placed in the PPA's glass holder, 15 to 16 millimeters of cigarette tip are available to the smoker's lips. The Extended Filter was used in these tests to remove any doubt that the PPA leaves enough tip available for the smoker to hold a Barclay-type cigarette in his lips in his normal way. (See p. 24, below.)

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Merit	32.4	33.2
Barclay	73.1	45.6
Extended Filter[4/]	72.2	32.2

In other words, when Barclay is held in a mouthpiece -- or in a dental dam in the Commission's smoking machine -- on average only 26.9% (100% minus 73.1%) of the puff is drawn through the tobacco rod as opposed to the dilution perforations. However, when Barclay is held in an average smoker's lips, more than twice as much, 54.4% (100% minus 45.6%) of the puff is drawn through the tobacco rod. Moreover, the greater tobacco rod delivery during the puff duration means that the smoke is delivered at a much higher flow rate, and, as we have demonstrated in prior submissions, the

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4/ As noted earlier, the Extended Filter cigarette was included in the study to determine whether any drop in Barclay's dilution might be caused by a failure to provide smokers with an adequate length of filter to hold in their lips. In fact, the Philip Morris Extended Filter cigarette recorded a somewhat greater drop in dilution than Barclay regardless of how much of the filter was made available to smokers. We believe that this was because of tighter quality control in the manufacture of the Extended Filter cigarettes -- holes or tears in the non-porous plugwrap of a bypass filter can moderate the dilution drop somewhat. Accordingly, it appears that unless the Commission modifies the holding device in its smoking machine as has been suggested, other manufacturers may be able to exploit the present loophole even more effectively than Brown & Williamson.

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efficiency of the Barclay filter declines sharply at those high flow rates. Accordingly, as measured by FTC method, when Barclay's unlit dilution is reduced to the 45% range, it delivers about 8 mg. "tar."

For reasons described below, the principal U.S. Testing study was performed with unlit cigarettes. Over 100 smokers were also tested with lit cigarettes, however, and the results were completely consistent:5/

Brand	Average Percent Dilution (cigarette held in mouthpiece)	Average Percent Dilution (cigarette held in lips)
Respondent's Own Brand	37.7	37.0
Carlton	76.3	75.7
Merit	42.7	42.9
Barclay	79.9	55.6
Extended Filter	80.0	42.0

Again, these lit data confirm that the smoke component of a Barclay puff more than doubles when the cigarette is held in the lips, soaring from 20.1% to 44.4%, with

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5/ The dilution of any diluted filter cigarette increases upon lighting. This is because the burning coal impedes air flow through the rod, and dilution air accordingly becomes comparatively easier to draw.

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an attendant increase in smoke flow rate and concomitantly reduced filtration efficiency.

It might be observed that, of the 500 smokers in U.S. Testing's demographic sample, only 8 were regular smokers of Barclay cigarettes. U.S. Testing questioned whether this sample was sufficient to determine whether the drop in Barclay dilution was experienced not only by smokers generally, but specifically by regular Barclay smokers. Accordingly, a separate sample of 47 Barclay smokers was obtained. The data for those 47 smokers were essentially identical to those for the panel as a whole:

Unlit Data

Brand	Average Percent Dilution (cigarette held in mouthpiece)	Average Percent Dilution (cigarette held in lips)
Respondent's Own Brand (Barclay)	73.4	43.1
Carlton	71.1	70.2
Merit	31.4	31.3
Barclay	76.8	49.9
Extended Filter	71.9	33.4

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Brand	Lit Data: Average Percent Dilution (cigarette held in mouthpiece)	Lit Data: Average Percent Dilution (cigarette held in lips)
Respondent's Own Brand (Barclay)	79.8	54.6
Carlton	80.7	79.4
Merit	41.7	41.0
Barclay	82.8	60.2
Extended Filter	80.5	45.4

As we have demonstrated to the Commission in the past, it is possible to measure the "tar" delivery of cigarettes by FTC method at varying dilutions by modifying the tipping paper to control ventilation. Based on such measurements of commercial cigarettes at varying dilutions, Barclay KSSP at the dilution obtained when smoked on a smoking machine or through a mouthpiece has a "tar" delivery similar to that of Carlton KSSP, about 1 mg. However, Barclay KSSP at the dilution obtained when smoked in the lips has a "tar" delivery similar to that of Merit KSSP, about 8 mg.

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2. Methodology of the United States Testing Study

The study conducted by U.S. Testing was rigorous, objective and complete. The sample was large, scientifically selected and representative of the general smoking population. No one connected with Philip Morris participated in the testing in any way. The test subjects were not aware of the sponsor or the purpose of the study, and particular care was taken to prevent the subjects from seeing any of the data generated by the PPA.

As noted above, each test subject puffed five brands of cigarettes -- his own brand, Barclay, Carlton, Merit, and an Extended Barclay-type Filter cigarette. All commercial cigarettes were purchased by U.S. Testing from regular outlets, and were not preselected in any way. If a subject's regular brand was a 100 mm. product, Barclay 100's, Carlton 100's, and Merit 100's were used; if a subject's regular brand was a mentholated product, Barclay Menthol, Carlton Menthol, and Merit Menthol were used.

Each test subject puffed first on one of his own cigarettes to accustom him to the machine. The order of presentation of the other cigarettes was

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rotated; the test subject was not permitted to see the names on any of the cigarettes. Each cigarette was placed in turn in the machine's holder with the mouth-end protruding at least 10 mm.[6/] A mouthpiece was then placed on the mouth-end of the cigarette, and the cigarette was puffed by the subject three times. The mouthpiece was then removed, and three puffs were taken with the cigarette held directly in the subject's lips.[7/]

For a number of reasons, the principal study was done on unlit cigarettes. First, the cigarette industry has traditionally measured dilution with unlit cigarettes, and it was desired to remain as close to the customary practice as possible. Second, lighting the cigarette destroys it, making it impossible to recheck the cigarette later for anomalies. Third, because the vessel containing a lit cigarette must be cleared after each puff and cleaned periodically,

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6/ Because of the greater distance of the ventilation perforations from the mouth-ends of the Barclay 100 and Extended Filter cigarettes, 13 mm. of the Barclay 100 filter were made available to the smokers' lips, and at least 15 mm. of the Extended Filter were made available to the smokers' lips.

7/ Analysis of spent Barclay filters suggests that some smokers permanently crush or crimp the peripheral channels of the bypass filter when smoked in the lips. For this reason, measurements were always made first with the mouthpiece.

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dilution testing with lit cigarettes is a substantially slower process. Finally, and perhaps most important, requiring a smoker to puff lit cigarettes of an unfamiliar brand might in theory cause him to alter his regular smoking patterns.8/ Nevertheless, to make certain that the use of unlit cigarettes did not distort the results, U.S. Testing undertook to measure dilution on lit cigarettes for at least 100 subjects. As noted above, the results achieved on lit cigarettes were fully consistent with and confirmed the results of the unlit cigarette tests.

As previously noted, a copy of the U.S. Testing report is being submitted to the Commission together with this memorandum. In addition, all cigarettes, mouthpieces, butts, and PPA data tapes have been retained, and will be made available to the Commission upon request.

To our knowledge, no more intensive study has ever been made of the dilution of any cigarettes. The conclusion is clear and unmistakable: Alone among all

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8/ For example, because Barclay is substantially higher in "tar" than 1 mg. cigarettes such as Carlton or Cambridge, it was feared that a Carlton or Cambridge smoker might not feel comfortable taking his normal puff on a lit cigarette such as Barclay.

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cigarettes, the dilution of Barclay -- and the other now-proliferating brands fitted with the same bypass filter -- drops dramatically when smoked in the mouth, to the 45% region. At 45% dilution, Barclay is an 8 mg. "tar" cigarette by FTC method.

B. Response to the Commission's Questions Regarding the Philip Morris Dilution Study

The questions raised in Attachment II to the Commission's letter of December 15, 1981 regarding the methodology of the Philip Morris dilution studies have been rendered academic by the U.S. Testing study. Nevertheless, we have always been fully satisfied that there is no legitimate basis for challenging the methodology employed in the Philip Morris studies, and we respond to each of the Commission's questions as follows:

1. "Questions have been raised about the impact of the sample size on the validity and reliability of the results."

The initial study submitted by Philip Morris to the Commission included data for 45 smokers. Every one of these smokers registered a substantial drop in the dilution of Barclay cigarettes when smoked in the lips, and none of these smokers registered a substantial

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drop in dilution for any other cigarette brand. The likelihood of such a result being obtained purely by chance is negligible. The consistency and magnitude of Barclay's drop in dilution are significant by any statistical test. Moreover, samples of the size involved in the Philip Morris dilution study, or smaller, are frequently relied upon in clinical research and objective, product-characteristic testing.

As discussed above, the studies conducted by U.S. Testing included more than 500 smokers and also produced consistent and substantial decreases in dilution when Barclay was puffed in the smokers' lips.

2. "Questions have been raised regarding whether the use of Philip Morris employees as subjects biases the results."

In the regular course of business, Philip Morris conducts numerous studies of its own cigarettes, proposed new cigarettes, and competitors' cigarettes. The subjects employed in the original Barclay dilution study were obtained from the regular panels used at Philip Morris for product testing, and represent a good mixture of smokers of different habits who regularly smoke different kinds of cigarettes. Over the years, we have found that Philip Morris employees can be relied upon

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to give valid, reproducible data, and the company relies upon those data in making significant product and marketing decisions. We believe that every other company in the cigarette industry, and numerous companies in many other industries, commonly rely on their own employees for product testing.

It should be emphasized that the Barclay studies did not call for subjective impressions. Rather, the tests measured the impact on dilution, as measured by scientific equipment, when Barclay and other cigarette brands are puffed in smokers' lips. It is difficult to believe that the lips of Philip Morris employees function any differently from those of smokers generally.

As noted above, the same dilution drop for Barclay was recorded by FTC staff members and by Brown & Williamson employees and consultants. (See note 2, above.) Moreover, the subjects employed in the large-scale U.S. Testing studies were not affiliated with Philip Morris or any other cigarette manufacturer in any way.

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3. "Questions have been raised regarding whether the fact that some of the subjects may have known the purpose of the study biases the results."

At least three points should be noted in response to this inquiry. First, the initial dilution studies of Barclay cigarettes were conducted soon after introduction of the product, long before Philip Morris had taken any position whatever with regard to the bypass filter. Our only real "purpose" at that time was to better understand a new competitive product.

Second, we seriously doubt that many of the persons involved in the tests knew or cared what "purpose" Philip Morris may have had in mind. Testing new products -- both our own proposed cigarettes and competitive brands -- goes on continually at Philip Morris, and our regular subjects consider such tests a matter of routine.

Third, even if some member of the panel had divined the nature of the study being conducted, we think it would have been extremely difficult, if not impossible, for him to have biased the results. This was not a subjective study in which the candor and objectivity of the subjects were relied upon. The

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subjects were merely seated with their back to a machine and asked to puff on cigarettes in their regular manner. Moreover, all participants in the study produced substantially similar results; the possibility that some panelists may have known something about the study could not have produced this remarkable consistency.

All of the more than 500 test subjects employed by U.S. Testing in its dilution studies were told absolutely nothing about the sponsor or purpose of the studies, or the kind of data being generated.

4. "Questions have been raised regarding whether the use of Philip Morris employees to conduct this research biases the results."

The personnel that conducted the original dilution measurement studies were nonprofessional Philip Morris employees who regularly conduct panel testing of various kinds. They were fully familiar with the operation of the dilution measurement equipment, and were instructed to perform an objective, rigorous test to measure the parameters of cigarette puffing in a fair and accurate manner. While incorrect operation of the equipment could lead to distorted data, those distortions generally result in physically improbable

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flow rates and are obvious upon inspection of the data. The data generated in the studies in question have been scrutinized in considerable detail. Those data are internally consistent, and also consistent with proper operation of the equipment and proper test procedures.

The large-scale studies performed by U.S. Testing were conducted exclusively by that testing organization's own personnel.

5. "Questions have been raised regarding whether the special apparatus designed by Philip Morris for this research to measure air dilution prevents normal smoking behavior, and regarding whether the placement of the dental dam on the cigarette filter biases the results against Barclay."

In order to measure cigarette dilution during human puffing, the mouth-end of the cigarette must remain open and unobstructed for the smoker to puff upon and both the end of the rod and the dilution perforations must be encapsulated so that the flow of air through each can be measured. Subject to those inherent design requirements, the equipment developed by Philip Morris engineers measures with great accuracy the dilution of cigarettes puffed by human smokers with the least

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possible interference with normal smoking behavior. While the cigarette must be encapsulated, the light glass holder used with the PPA is connected to the machine by flexible tubing and can be moved freely. Test subjects are thus able to assume a posture as close as possible to that of everyday, relaxed smoking.

Apparently the primary concern reflected in the Commission's question 5 is the question, raised several months ago by the Commission's staff, whether a sufficient length of cigarette filter extends from the end of the glass PPA holder to permit the smoker to hold the cigarette in his lips in his customary manner. The way that smokers hold and use cigarettes has been a matter of interest to Philip Morris for many years, and our continuing evaluations have led us to conclude that smokers do not typically insert more than about nine millimeters of a cigarette into their lips, which is safely less than the amount of filter extending from the end of the glass PPA holder. Rather than rely on that conclusion, however, we prepared cigarettes with extended bypass filters containing ventilation perforations 17 millimeters from the mouth-end of the filter, so that a full 15 to 16 millimeters could be made available for the smoker's lips. These extended

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bypass filter cigarettes have been used in internal Philip Morris testing, and were used, in addition to the commercially marketed Barclay cigarettes, with the more than 500 subjects in the large-scale U.S. Testing studies. These tests confirm that, no matter how much of the filter is available for the smoker's lips, the dilution of Barclay drops enormously.

In its October 23, 1981 submission, Brown & Williamson appears to argue that the PPA might give incorrect results because it prevents smokers from blocking the ventilation perforations of cigarettes with their fingers. We fail to understand, and B&W has not explained, how the necessary encapsulation of the ventilation perforations of Barclay and of all other cigarettes tested on the PPA in any way affected the uniform results -- i.e., that Barclay's dilution always dropped significantly when puffed in the lips but not when puffed in the mouthpiece, and that the same phenomenon did not occur for any other brand.

In any event, in our experience, the blockage of ventilation perforations by smokers is rare. Cigarettes are normally and comfortably held near their center of gravity, which is far from the ventilation perforations of any cigarette. Moreover, many smokers

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remove their fingers entirely from the cigarette during puffing, and it would be especially awkward and uncomfortable to hold one's fingers over the perforations during a puff.

Even if one were to assume that a greater amount of hole-blockage occurs in normal smoking, it merits emphasis that the hole-blockage issue is altogether different from the issue raised by the bypass filter. It is not the smoker, but the manufacturer, that causes Barclay to deliver far more "tar" than other products measuring 1 mg. by current FTC method. An educated smoker of another brand may easily avoid interfering with the filter's ventilation, but the smoker of Barclay, through no misuse of his own, smokes a cigarette that has a substantially lower dilution in his lips than it has on the current FTC machine.

Indeed, it is ironic that Brown & Williamson appears to subscribe to the hole-blockage thesis, because of all cigarettes on the market, Barclay would be the most dramatically affected by that kind of misuse. Barclay employs an extremely low efficiency filter, and the four peripheral grooves draw dilution air through only a fraction of the perforations in the tipping paper. Accordingly, wholly apart from the occlusion caused

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by the smoker's lips, blockage of only a very few of Barclay's ventilation perforations would result in an enormous increase in "tar" delivery.

6. "To what extent did the data for each subject tested vary? Does the raw data for each subject still exist? Can it be made available to the Commission staff?"

Smokers are not machines, and all smokers' puffs vary somewhat from puff to puff. Nonetheless, the Puff Parameter Analyzer has tended to show remarkably consistent results for each given smoker. In particular, Barclay's dilution appears to drop substantially on every puff.

All data developed in both the original Philip Morris study and the large-scale U.S. Testing studies have been retained, and will be made available to the Commission upon request.

7. "What cigarette did each subject tested customarily smoke? If they smoked a cigarette during the air dilution test different from their customary cigarette, what impact, if any, did this fact have on the results? Was each subject tested also tested on their customary cigarette? If not, why not?"

The participants in the original Philip Morris study were smokers of a variety of cigarettes.

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Identification of the specific brands will be made available to the Commission upon request. The customary cigarettes of smokers were not included in the original Philip Morris dilution study.

It should be noted that most dilution measurements have been made by having smokers puff unlit cigarettes. One reason for this was to minimize any possible distortion that might occur in a smoker's puffing pattern by exposing him to a cigarette with smoke characteristics different from those of his customary brand. For example, because Barclay delivers many times more "tar" than 1 mg. cigarettes such as Carlton or Cambridge, it was feared that a Carlton or Cambridge smoker might not feel comfortable taking his regular puff on a lit cigarette such as Barclay.

In the large-scale study conducted by U.S. Testing, the regular brands of test subjects were in accordance with the demographics of the smoking population generally. The customary brand of each test subject was noted, and every subject was tested with his regular brand. As noted above, over 100 of the test subjects in the large-scale U.S. Testing study were tested with lit as well as unlit cigarettes. The measurements on lit cigarettes indicated the same

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dramatic drop in the dilution of Barclay when smoked in the lips.

II. BROWN & WILLIAMSON'S COTININE EXPERIMENT DOES NOT SUPPORT ITS POSITION THAT BARCLAY'S "TAR" DELIVERY IS THE SAME AS THAT OF OTHER BRANDS MEASURED AT 1 MG. "BY FTC METHOD."

Brown & Williamson has been unable to refute the overwhelming evidence presented in the dilution studies. Instead, B&W relies primarily on the theory that valid conclusions about the "tar" deliveries of specific cigarette brands can be drawn from an analysis of smokers' bodily fluids, in particular, measurement of plasma cotinine.

On its face, this theory is flatly inconsistent with the entire philosophy of smoking machine testing that has informed the Commission's "tar" and nicotine determinations for many years. The Commission has sought to measure all cigarettes on a standardized machine, with standardized characteristics and smoking parameters, to avoid variations and distortions introduced by human physiology and individual behavior. The simple change in the standardized holding device proposed by Philip Morris will close the loophole now being exploited by B&W and will restore comparability of results to the testing program.

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Nevertheless, since the Commission invited comments on B&W's cotinine presentation, we have undertaken an analysis of that presentation, with the assistance of three of the most prominent experts in this area of research, Dr. Herbert McKennis of the University of Miami, Dr. Paul Larson of the Medical College of Virginia, and Dr. Neal Castagnoli of the University of California. These scientists, whose comments are submitted herewith as Exhibits 1-3, lead us to conclude that the experiment advanced by B&W is scientifically unsound.

A. B&W's Cotinine Experiment Is Scientifically Unsound.

The flaws in Brown & Williamson's presentation are numerous and fundamental.

Brown & Williamson's arguments are predicated upon an unreasonably simplistic view of nicotine and its metabolism. B&W's thesis proceeds from the assumptions that (i) "[c]otinine is the first and primary metabolic product of nicotine;"[9/] (ii) all nicotine in smoke is absorbed into the lungs; (iii) exactly 70%

9/ Submission to the Federal Trade Commission on behalf of Brown & Williamson Tobacco Corporation at 35 (October 23, 1981) (emphasis in original).

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of that nicotine turns promptly into cotinine; and (iv) all cotinine distributes itself evenly throughout the body and disappears with a half-life of 30 hours. Each and every one of these assumptions is unsupportable and flows from a drastic oversimplification of the extraordinarily complex and only partly understood in vivo metabolism of nicotine.

First, much has been written in the scientific literature about cotinine, and there are substantial uncertainties on many issues; but one point on which there has always appeared to be consensus is that cotinine is not the first metabolic product of nicotine.

Second, not all nicotine in cigarette smoke is absorbed into the lungs. Some smokers inhale more deeply or longer than others, which would lead to greater absorption. Even for a given smoker, the degree of absorption may vary with the nicotine composition of the smoke and other factors.

Third, not all nicotine is metabolized, nor is the fraction a constant 70%. Some nicotine is excreted directly in the urine, the exact proportion depending on a number of biological and physiological factors which vary from subject to subject and are not

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always constant even in a single individual. In particular, low urine pH will invariably lead to considerably greater nicotine excretion and concomitantly lower metabolization.

Moreover, not all metabolized nicotine turns into cotinine. The primary metabolites of nicotine are believed to be nicotine 1'-N-oxide, 5'-hydroxynicotine, isomethylnicotinium ion, and perhaps nornicotine. It is generally believed that 5'-hydroxynicotine then forms cotinine, as well as nicotine Δ 1'(5')-iminium ion and γ-(3-pyridyl)-γ-methylaminobutyric acid, the latter of which is believed to reach equilibrium with cotinine. Cotinine transforms into a number of further metabolites including cotinine methonium ion, cotinine N-oxide, hydroxycotinine, and γ-(3-pyridyl)-γ-oxo-N-methylbutyramide, some of which are metabolized further.

Fourth, B&W's facile assertion that cotinine is a "small lipid molecule" and therefore may be assumed to distribute itself evenly throughout the body lacks scientific demonstration. On the contrary, researchers have concluded that nicotine and its metabolites concentrate in various proportions in different parts of the body.

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Accordingly, in the real world, the degree of formation of cotinine or any other nicotine metabolite varies from person to person, and probably varies for a given person with dietary, environmental, and physiological factors. In particular, the pharmacokinetics of nicotine appear to depend substantially upon dose. At high doses of nicotine, a greater proportion is excreted in the urine and a lower proportion of cotinine is formed.

Because of the complexity of nicotine metabolism and the absence of reliable dose-response information, there is serious question among scholars as to whether cotinine measurements have any validity for making comparisons among different cigarette brands. Even if one were to assume that such studies could be conducted, however, the experiment performed by B&W contains substantial methodological problems.

For example, the gas chromatographic methods relied upon by Gori are not adequately specific; a number of compounds other than cotinine may give a chromatographic peak indistinguishable from that of cotinine unless mass spectrographic or other techniques are employed to discriminate among the compounds. In addition, Gori's failure to use an internal standard casts serious doubts

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on the validity of his results. Moreover, while the notion that every test subject serves as his own control may make sense in the abstract, it necessarily assumes that there are no changes in the diet, environment, or stress levels of the subjects. Such assumptions are highly questionable and have not been justified.

In view of the lack of rigor in Gori's methodology, it is not surprising that some bizarre data have been generated. For example, according to Table 4 in the Darby and McNamee paper, Gori's test subject No. 28 had a plasma cotinine level of 223 mg./ml. prior to switching from Barclay to Cambridge cigarettes. After smoking 52 Cambridge cigarettes a day for three days, his plasma cotinine level dropped to 42 mg./ml. Given the 30-hour cotinine half-life assumed by B&W, that subject's plasma cotinine level three days after switching from Barclay should have been higher than 42 mg./ml. even if he did no smoking at all. In short, B&W's data suggest that smoking Cambridge cigarettes removes cotinine from a smoker's blood.10/

10/ It should also be noted that the statistical treatment of Gori's data appears highly dubious. For no apparent reason, the data points for Gori's first panel were assumed to fall into a "normal" distribution, and the data points for the second panel were assumed to fall into a "lognormal" distribution. There was also

[Footnote continued on following page]

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For all of these reasons, and the reasons elaborated in the attached comments of Drs. McKennis, Larson and Castagnoli, B&W's cotinine data are scientifically invalid and unsound. B&W's cotinine experiment does not refute the clear evidence of the duplicitous operation of the Barclay filter demonstrated by the Philip Morris and U.S. Testing dilution studies, and confirmed by other substantial evidence presented to the Commission.

B. The Data Underlying the B&W Experiment Confirm the Results of the Dilution Studies Showing that Barclay's "Tar" Delivery Substantially Exceeds That of 1 mg. "Tar" Cigarettes by FTC Method.

As discussed above, the cotinine experiment proffered by Brown & Williamson is without scientific value. Even if one were to assume that B&W's data had some validity, however, they would not support B&W's claims regarding Barclay. Indeed, the data generated

[Footnote continued]
a huge variation in the data for each brand: Using Gori's "standard errors" (we assume Gori meant standard deviations), it appears that all of the means overlap within two standard deviations, and two or three individual standard deviations often exceed the individual means. It is extremely unlikely that statistically significant conclusions can be drawn from such data.

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in B&W's experiment actually suggest that Barclay delivers substantially higher "tar" than brands, such as Cambridge or Carlton, which deliver 1 mg. "tar" by FTC method.

It should be noted that the graphs attached to the Darby and McNamee paper submitted by B&W only show predicted plasma cotinine levels for Gori's subjects. B&W did not attempt to fit Darby and McNamee's model to the actual data obtained by Gori. We have done that for them.

Attached hereto as Exhibits 4-7 are graphs applying the Darby and McNamee model to actual data obtained by Gori. As these exhibits make clear, there is a huge increase in the plasma cotinine levels of the subjects' blood when they switch from Cambridge or Carlton to Barclay, frequently 100% to 200% or more. B&W attempts to explain away this phenomenon by claiming that Barclay cigarettes, tested under standard FTC machine conditions, have the same "tar" delivery as Cambridge or Carlton -- 1 mg. -- but twice the nicotine delivery -- 0.2 mg. for Barclay, as compared with 0.1 mg. for Cambridge and Carlton. On this premise, B&W asserts that if Barclay, Cambridge and Carlton in fact deliver the same level of "tar," cotinine analysis of

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Barclay should indicate twice the nicotine delivery of the other brands.

Brown & Williamson appears to have indulged, however, in some convenient rounding. According to the Commission's official report of December 15, 1981, the nicotine delivery of Barclay under machine smoking conditions is 0.15 mg.; the nicotine delivery of Cambridge and Carlton under identical machine smoking conditions is 0.11 mg. In short, under machine conditions, Barclay does not deliver twice the nicotine of Cambridge or Carlton, as B&W has asserted; instead, Barclay is at most 36% higher in nicotine. If Barclay was in fact the 75% dilution-1 mg. "tar" cigarette B&W claims it to be, then forced switching from Cambridge or Carlton to Barclay could increase the plasma cotinine level by no more than 36%. Gori has demonstrated, however, that the increase in plasma cotinine level is far greater than that.11/

Because of behavioral and pharmacokinetic factors frequently discussed in the literature, if Barclay

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11/ With respect to Now cigarettes, B&W's "rounding" may have gone even further. The December 15, 1981 Commission report lists Now's nicotine delivery by FTC method as 0.22 mg., but B&W's papers claim that Now's nominal nicotine delivery is 0.1 mg.

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produces a plasma cotinine level 100 to 200 percent higher than that of Cambridge or Carlton -- as reflected in the data presented by B&W -- one can reasonably infer that, under equivalent machine smoking conditions, Barclay would deliver far more than 200 percent more "tar" than Cambridge or Carlton. Gori made the point himself in the B&W submission:

> "First, it is necessary to realize that smokers vary in their appetite or demand for smoke. In this situation a low yield cigarette is likely to be utilized more completely than high yield cigarettes. The analogy is that of offering water in pint and gallon containers to a group of thirsty people. Most pint containers are likely to be totally emptied, while many of the gallon containers will remain variously full. Thus in measuring uptake from different cigarettes, one can expect a greater variability of results with smokers of high yield cigarettes than otherwise. Also, the behavior and perhaps the smoke metabolism of smokers of high yield cigarettes is most likely different from that of low yield cigarette smokers. Because of this, the relationship of smoke residues in smokers of high yield cigarettes does not follow a one-to-one proportion, when matched to the nominal FTC yield of the cigarette smoked. For instance a smoker of a 10 milligram cigarette can not be expected to have 10 times the smoke residues in his system when compared to a smoker of a 1 milligram cigarette. Based on some available fragmentary evidence, he is likely to have less than a ten-fold increment, and the precise relationship can not be predetermined with accuracy at the

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present state of the art." Letter from Gio Batta Gori, D.Sc., MPH to Martin London, Esquire, at 4 (October 22, 1981).

Significantly, the smokers utilized in the Gori experiment were generally smokers of 1 mg. delivery cigarettes such as Carlton and Cambridge. Using Gori's reasoning, it is not surprising that when such smokers were forced to switch to an 8 mg. cigarette such as Barclay, their plasma cotinine levels did not go up eightfold, but only a few hundred percent.

The inescapable conclusion is that B&W's own data demonstrate that Barclay delivers substantially more "tar" than other brands ranked by the current FTC method at 1 mg.

CONCLUSION

The Commission's investigation of Barclay cigarettes has been pending since May 1981, and during that time extensive evidence has been submitted by most of the United States cigarette industry establishing the duplicitous character of the bypass filter. The large-scale demographic study conducted by U.S. Testing proves beyond any doubt that the dilution of Barclay cigarettes when smoked in the lips is far less than

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the dilution of Barclay cigarettes when puffed in a smoking machine. No other cigarette experiences any substantial drop in dilution. Barclay's dramatic drop in dilution necessarily results in a delivery of "tar," nicotine, carbon monoxide, and other smoke components that is substantially higher than that of other cigarettes with similar rankings by current FTC method. Brown & Williamson's own cotinine experiment, despite the dearth of scientific detail and the apparently endemic methodological errors, provides further evidence of the duplicitous character of the bypass filter.

The simple modification to the holding device in the Commission's smoking machine recommended by Philip Morris last year, and now supported by most of the industry, would readily and conveniently close the loophole in the Commission's testing procedure being exploited on a large scale by Brown & Williamson with Barclay, Kool Ultra and Viceroy Ultra Rich Lights. To maintain the integrity of the Commission's "tar" and nicotine rankings, and to assure consumers a fair basis for comparing cigarette brands, we urge that that modification be made forthwith.

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